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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,066	10/06/2006	Vitaly Dzhavakhia	KOR PELA MF3	1571

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,066	DZHAVAKHIA ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1,3,4 and 8-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-7,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 04/04/08 is acknowledged. The traversal is on the ground(s) that the protein structure of MF2 disclosed by Dzhavakhia et al (US 6, 528, 480 B1) does not share sequence homology with the MF3 of the instant claims, and that MF2 of Dzhavakhia et al has MW of 7,239 Daltons derived from *Bacillus thuringiensis*, while the MF3 of the instant claims has different structure and a MW of 17,600 Daltons derived from *Pseudomonas fluorescence*. This is not found persuasive because there is no specific sequence homology, molecule weight, structure or a source of the polypeptide recited in claim 1 of the instant application. The claim requires an active fragment or functional derivative of SEQ ID NO: 1 that is capable of effecting resistance of a plant against diseases. Dzhavakhia et al (US 6, 528, 480 B1) teach an isolated polypeptide that protects plants from pathogen infection. MPEP §1850 states that unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. Therefore, since claim 1 is taught in the prior art, there is no special technical feature that links the invention of Group I to any of inventions I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-15 are pending.

Claims 1, 3-4, and 8-13 are withdrawn from consideration as being directed to the non-elected invention.

Claims 2, 5-7 and 14-15 are examined.

Sequence Listing

The sequence listing of 06/15/06 has been entered. However, the application does not comply with the sequence Rule §1.821 through 1.825 because the specification, pages 33 (lines 1-2, 4-5) and 36 (lines 22-23), recites sequences with no sequence identifier, SEQ ID NO. Nucleotide and /or amino acid sequences as used in §1.821 through 1.825 are interpreted to mean unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides in patent applications. The 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is respectfully requested to identify the sequences on pages 33 (lines 1-2, 4-5) and 36 (lines 22-23) or to submit a new Sequence Listing, which comprises said sequences. The specification should also be amended to recite SEQ ID NO:

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 2, 5-7 and 14-15 are objected to for depending upon non-elected claim 1, drawn to the non-elected invention. In the interest of compact prosecution, claim 2 is considered to contain all limitations of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5-7 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the recitation of “bioactive” polypeptide and “functional derivative” which are not clearly defined in the specification. The terms/phrase are open to individual interpretations. Dependent claims 5-7 and 14-15 are included in the rejection because they do not obviate the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5-7 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA sequence encoding SEQ ID NO: 1, a vector comprising said DNA sequence, host cell/plant transformed with said vector , does not reasonably provide enablement for an isolated DNA sequence encoding a bioactive fragment or functional derivative of SEQ ID NO: 1 or a fragment of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to an isolated DNA sequence according to SEQ ID NO:2, or fragment thereof, encoding the polypeptide MF3 of SEQ ID NO: 1 or its bioactive fragment or functional derivative thereof, wherein said DNA fragment may contain degenerate codons; a vector comprising the DNA; a transgenic plant or plant cell culture comprising the vector; a host cell stably transformed or transfected with the vector; said transgenic plant or plant cell culture having resistance against diseases caused by specific pathogens. In contrast, the specification provides guidance for the isolated DNA sequence of SEQ ID NO: 2 encoding SEQ ID NO: 1, a vector comprising said DNA sequence, a host cell/plant stably transformed with said vector.

Applicant has not provided guidance for how to identify or obtain all the DNA sequences encoding polypeptides having both the structural and functional limitations as recited in the claims. The breadth of the claims encompasses nucleotide sequences obtainable by modifications including multiple deletions and/or substitutions of nucleotides in SEQ ID NO: 2. However, Applicant has not taught which regions in SEQ ID NO: 2 or 1 would tolerate such modifications. Therefore, Applicant has not provided guidance for modifications to SEQ ID NO: 1 or 2 that resulted in DNA sequences encoding polypeptides having both the structural and functional limitations as recited the claims.

Applicant does not teach all DNA sequence sequences that are fragments of SEQ ID NO: 1 which may contain degenerate codons. See, for example, Accession no. ABD14347 having 90% sequence identity to Applicant's SEQ ID NO: 2 (see attached alignment of sequences) and has no known disease resistance activity.

While mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims. One skilled in the art would expect any tolerance to modification for a given DNA/protein to diminish with each further and additional modification or multiple substitutions/ deletions. One skilled in the art would have to make all possible nucleotide/amino acid substitutions and deletions in the 486 nucleotide long sequence of SEQ ID NO: 2 or in the 161 amino acid sequence long of SEQ ID NO: 1 and test all sequences that meets the structural limitations to determine which also meet the functional limitation. One would also have to test and evaluate disease resistance activity of each of said DNA

sequences upon expression a transgenic plant. These tests are considered undue and excessive.

In addition, since the working example disclosed in the specification is limited to unmodified SEQ ID NO: 2, the ability of SEQ ID NO: 2 to encode a polypeptide having disease resistance activity cannot be extrapolated to any variant thereof, absent specific guidance.

Therefore, given the breadth of the claims, the nature of the invention, the unpredictability in the art with respect to DNA/protein modifications, the limited guidance and working examples in the specification as discussed supra, and the state of the prior art, the claimed invention is not enabled throughout the broad scope. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988). See, also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 2, 5-7 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated DNA sequence according to SEQ ID NO:2, or fragment thereof, encoding the polypeptide MF3 of SEQ ID NO: 1 or its bioactive fragment or functional derivative thereof, wherein said DNA fragment may contain degenerate codons; a vector comprising the DNA; a transgenic plant or plant cell culture comprising the vector; a host cell stably transformed or transfected with the vector; said transgenic plant or plant cell culture having resistance against diseases caused by specific pathogens. In contrast, the specification describes an isolated DNA sequence encoding SEQ ID NO: 1, a vector comprising said DNA sequence, a host cell/plant stably transformed with said vector.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof.

In Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997);" A representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at

1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed."

The specification does not describe the composition and structure of an active fragment, a fragment or a functional derivative of SEQ ID NO: 1 or 2. No description is provided for a polypeptide or DNA other than SEQ ID NO: 1 or 2.

The specification does not disclose a single variant of SEQ ID NO: 1 or 2 having both the structure and function as recited in claims. A substantial variation in structures and function is expected among the active fragments and functional derivates of SEQ ID NO: 1 being capable of disease resistance, and among the DNA sequences encoding said polypeptides. Therefore, the specification neither describes a representative number of species of the genus of DNA and polypeptide sequences of the claims nor provides structural-function domains common to all desired sequences. Since the specification does not provide adequately written description for the DNA sequences as broadly claimed, vectors, host cells and transgenic plants comprising said DNA sequences are similarly not described.

Therefore, for all the reasons discussed above, a skilled artisan would not have reasonably concluded that Applicants were in possession of the invention as broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 2, 5-7 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Djavakhia et al (WO97/05165)

Dzhavakhia et al teach an isolated DNA encoding a polypeptide having antifungal and antiviral activity; a vector comprising said DNA, plant cell and plants stably transformed with said vector, wherein the plants exhibit resistance to *Phytopthora infestans* and TMV and PVX viruses. The polypeptide encoded by the prior DNA would be a bioactive fragment or functional derivative of Applicant's SEQ ID NO: 1. The prior art DNA sequence also represents a fragment of SEQ ID NO: 2, since no specific definitions or other structural characteristics that would distinguish the claimed DNA/polypeptide from the prior art DNA/polypeptide is disclosed. The resistance against nematode would be an inherent property, absent evidence to the contrary. See Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) where the Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of P. cepacia. A U.S. patent to Dart disclosed inoculation using P. cepacia type Wisconsin 526 bacteria

for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
7/17/2008

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638